Exhibit 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

TAMARA NEWSOME,

Plaintiff,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

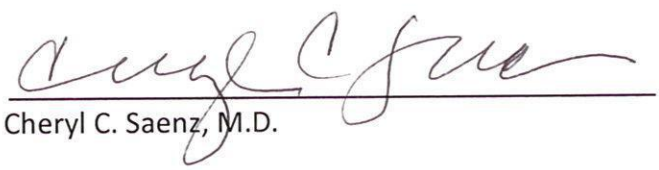
MDL NO. 16-2738 (FLW) (LHG)

Civil Action No.3:18-cv- 17586-FLW-LHG

EXPERT REPORT OF CHERYL C. SAENZ, M.D.

Case-specific opinions regarding Ms. Tamara Newsome

Date: May 28, 2024



Cheryl C. Saenz, M.D.

Diagnosis and Treatment of Ovarian Cancer

Tamara Newsome was born on November 7, 1961. On March 17, 2015, Ms. Newsome presented to the emergency department at White Oak Medical Center with complaints of dysuria and pelvic pain radiating to her abdomen. She also reported that she had symptoms of an upper respiratory infection and a fever. Urinalysis was negative for evidence of infection and a pelvic ultrasound was performed that revealed a very large irregularly shaped cystic lesion 10 x 11 x 8 cm with thickened nodular walls and internal septations. There was also noted to be a small amount of free fluid in the cul-de-sac. The interpretation of the mass by the radiologist was inconclusive with both cystadenoma (benign) and cystadenocarcinoma (malignant), being listed in the differential diagnosis. Ms. Newsome was discharged home with follow up to be scheduled with Dr. Ein, her general gynecologist. A CT scan of the abdomen and pelvis was performed on March 20, 2015, and that study identified a 12 cm multilobulated cystic mass in the pelvis to the right of midline consistent with a right ovarian neoplasm. Ms. Newsome was then admitted to Holy Cross Hospital on March 22, 2015, and seen in consultation by Dr. Albert Steren, a gynecologic oncologist.

On March 23, 2015, Ms. Newsome was taken to the OR by Dr. Steren and underwent a robotic-assisted total laparoscopic hysterectomy, bilateral salpingo-oophorectomy, omentectomy, right pelvic lymph node dissection, cystoscopy and placement of a Jackson-Pratt drain. Operative findings included a large right pelvic mass and a posterior cul-de-sac that was somewhat obliterated, consistent with pelvic adhesive disease. Dr. Steren also described that "[t]he right adnexa was stuck to the right pelvic sidewall under the cul-de-sac."[1] Both of these findings, that of the obliterated posterior cul-de-sac and the right adnexal mass being adherent to the right pelvic sidewall, are consistent with the behavior of endometriosis. Final pathology revealed a low grade endometrioid adenocarcinoma originating in the right ovary with extension to the uterine serosa. Because the remainder of the tissues that were removed at the staging operation were negative for disease, she was reported to have Stage IIA disease. These findings, along with an overall favorable prognosis, were explained to Ms. Newsome by Dr. Steren at the time of her postoperative visit on April 10, 2015. She was counseled that she would benefit from adjuvant chemotherapy and was referred to medical oncology.

Ms. Newsome was referred to Dr. Ravin Garg, who recommended that she be treated with taxane and platinum-based chemotherapy. As she reported that she was an ultrasound technician and she was concerned about the possible neuropathy associated with paclitaxel treatment, Dr. Garg substituted docetaxel for paclitaxel in her first cycle of chemotherapy on May 8, 2015. She had an allergic reaction to the Taxotere, but was able to complete the treatment along with receiving carboplatinum with additional solumedrol. For cycle #2 of chemotherapy, Dr. Garg switched back to paclitaxel and carboplatinum, but again Ms. Newsome had an allergic reaction to the taxane, and so received single agent carboplatinum only. She then completed an additional 4 cycles of single agent carboplatinum on August 28,

[1] NewsomeT-HCHMR-00151

2015. Overall, she tolerated the chemotherapy well, though she was admitted briefly to the hospital for neutropenic fever and anemia after cycle #6. Ms. Newsome has remained in remission from her ovarian cancer diagnosis since completing her chemotherapy in 2015. She had a negative CT scan in May 2023 and according to medical records, at the time of her last Telehealth visit with Dr. Garg on June 9, 2023, is still without evidence of disease.[2] Dr. Garg testified that although Ms. Newsome's cancer could come back after 5 years, he does not think it will,[3] and that "at five years, you know, once the scans are negative …we think, hey, you might be – you might be cured you know, forever."[4] In his deposition testimony, Dr. Steren states that he has no reason to disagree with Dr. Garg's opinion that it is unlikely that Ms. Newsome's cancer will return.[5]

Clinical Cancer Genetics

Ms. Newsome's cancer family history includes a father with renal cell carcinoma, a brother with a pheochromocytoma, a maternal uncle with prostate cancer and a paternal first cousin with salivary gland cancer and then 20+ years later prostate cancer. She also relates that when she was diagnosed with ovarian cancer, her maternal grandmother told her that she had a sister who had been diagnosed with ovarian cancer and survived to the age of 106.

Based on her personal history of ovarian cancer, Ms. Newsome's risk of carrying a gene mutation was high enough to justify genetic testing. Dr. Ein ordered genetic testing for Ms. Newsome through Myriad Genetics, and in December 2015, Ms. Newsome was informed that she was negative for a germline mutation in 25/26 genes tested; however, a variant of uncertain significance was detected in the MUTYH gene.

Ms. Newsome never actually had a consultation with a medical genetics counselor. This is an unfortunate lapse in her medical care as genetics counselors are responsible for not only interpreting the impact of positive results to patients, but also negative results. Had Ms. Newsome seen a genetics counselor, she would have inevitably been informed that because the genetic basis, if any, of her ovarian cancer has not been identified, this negative result does not necessarily mean that her cancer was sporadic (i.e., not attributable to an inherited predisposition). This is because of two important limitations of the test. First, not all inherited predisposition to cancer is attributable to the 26 genes that she was tested for. Research has identified other genes that when mutated can increase one's risk of cancer. Second, a small percentage of mutations in genes tested by this panel may be missed by current technology. Additionally, she has not had molecular profiling of her tumor to try to identify if there are somatic mutations in her tumor that would be targets for treatment with checkpoint inhibitors, or maintenance therapy.

Past Medical History

---

[2] NewsomeT-MOHA-MDR-000017.
[3] February 4, 2021 Deposition Transcript of Ravin Garg, MD, p. 115.
[4] February 4, 2021 Deposition Transcript of Ravin Garg, MD, p. 55, lines 2-6.
[5] February 17, 2021 Deposition Transcript of Albert Steren, MD, p. 55.

- Hypertension
- Anxiety disorder
- Tobacco use 10 years, last 1993

Past Surgical History

- Cesarean section*2
- Robotic-assisted TLH/BSO, omentectomy, right pelvic lymphadenectomy, cystoscopy

Obstetrical/Gynecologic History

- Menarche at age 14
- Menopause at age 50-51
- G3P2 with first child at age 31
- Breastfeeding – days to weeks with each child
- Oral contraceptives – 8-10 years
- Hormone replacement therapy - none

Summary

I have performed a thorough review of Ms. Newsome's medical records, the depositions of Tamara Newsome, Daniel Francois, Jr., Tae'lor Francois, Ravin Garg, M.D., and Albert Steren, M.D., as well as the Plaintiff Profile Forms, expert reports of Drs. Godleski and Clarke-Pearson, and the depositions of Dr. Clarke-Pearson. I have also reviewed the expert report of Dr. Teri Longacre, defense expert in the field of gynecologic pathology.

Ms. Newsome was diagnosed with Stage IIA low grade endometrioid adenocarcinoma of the right ovary in March 2015. With appropriate surgery and an optimal debulking by Dr. Steren, followed by chemotherapy as prescribed by Dr. Garg, Ms. Newsome's cancer entered remission and she has remained disease-free since 2015. Even though Ms. Newsome had no deleterious mutations identified in germline testing of 25 genes and only a variant of uncertain significance in the MUTYH gene on the Myriad panel, there is still a possibility that Ms. Newsome is carrying a germline mutation that science has yet to identify that contributed to her development of ovarian cancer.

Ms. Newsome's two primary risk factors for endometrioid ovarian cancer were her age and the endometriosis that was found by Dr. Steren at the time of her surgery. The obliteration of the pelvic cul-de-sac and the adherence of the right ovary to the right pelvic sidewall, described by Dr. Steren in his operative note, are classic findings for the adhesive disease caused by endometriosis. The presence of endometriosis adjacent to the endometrioid adenocarcinoma in Ms. Newsome's right ovary, was confirmed by the histologic analysis performed by Dr. Longacre. "The carcinoma is associated with endometriosis (Figures 3 and 4) (slide A8) as well atypical endometriosis (Figures 5-7) (slides A13 and A15)."[6] Examination of Figure 5 from Dr. Longacre's report demonstrates just how close in proximity the atypical endometriosis actually

[6] February 11, 2022 Expert Report of Teri Longacre, MD, page 7.

is to the endometrioid adenocarcinoma.[7] Dr. Clarke-Pearson's statement that "[t]here is no evidence of endometriosis by history, surgical evaluation, or pathologic testing,"[8] is thus incorrect.

As stated in my general causation report, the presence of endometriosis increases a woman's risk of developing endometrioid ovarian cancer by two - to threefold. That OR equates to a 100-200% increase in the risk of developing endometrioid ovarian cancer. Saavalainen and colleagues (2018), reported that women with ovarian endometriosis had an OR of 4.72 (2.75,7.56) of developing specifically endometrioid ovarian cancer, and even when the endometriosis was limited to the peritoneum there was still a twofold increase in the risk of endometrioid histology.[9] Based on the surgical findings at the time of her cancer surgery, as well as the microscopic identification of endometriosis and atypical endometriosis in Ms. Newsome's right ovary, Ms. Newsome most likely carried the diagnosis of both peritoneal and ovarian endometriosis. Thereby, the presence of endometriosis increased Ms. Newsome's risk of developing endometrioid ovarian cancer somewhere in the range of 100 - 372%. Although no distinct causal mechanism can be identified for Ms. Newsome's cancer, as is the case with all individual patients who develop ovarian cancer, endometriosis was most likely a substantial contributing factor. Dr. Steren, Ms. Newsome's gynecologic oncologist concurs, stating that "in most instances, the cause of ovarian cancer can't really be elucidated if they don't have a genetic predisposition." "We don't really know what causes them."[10]

In his expert report Dr. Clarke-Pearson states that Ms. Newsome did not have any risk factors for the development of ovarian cancer. At his deposition, however, he changed his opinion and agreed that her obesity contributed to her developing the disease, based on her BMI of > 30.[11] Olsen et al. (2013) identified an OR of 1.37 increased risk of developing ovarian cancer in women with a BMI between 30.0-34.0.[12] In his deposition, Dr. Clarke-Pearson characterizes an OR of 1.37 as only "a slightly increased risk of developing ovarian cancer."[13] He treats similar ORs associated with talc exposure very differently. In his expert report he writes that the "case-control studies show a 30-40% increased risk of EOC associated with genital talcum powder use,"[14] and he asserts that this OR has demonstrated that genital use of talc can cause epithelial ovarian cancer. It is unscientific (and reflective of a results-driven approach) to state when applied to obesity an OR of 1.37 only slightly increases a woman's risk of developing ovarian cancer, and yet when it is the OR associated with the genital application of talc that talc is causal in the development of the disease.

---

[7] February 11, 2022 Expert Report of Teri Longacre, MD, page 16.
[8] July 2, 2021 Expert Report of Daniel Clarke-Pearson, MD, page 17.
[9] Saavalainen, L., et al. Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology*. 2018; 131(6), 1095-1102.

[10] February 17, 2021 Deposition Transcript of Albert Steren, MD, p. 29, lines 13-17.
[11] March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 321, lines 3-12.
[12] Olsen C.M., Nagle, C.N., Whiteman, D.C., Ness R., Pearce C.L., Pike M., Rossing M.A., Terry K., Wu A., et al. (2013). Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. *Endocr Relat Cancer*, 20(2): 251-62.
[13] March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 320, lines 9-18.
[14] November 15, 2023 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD, page 11.

Additionally problematic is the fact that Dr. Clarke-Pearson cites to Dr. Godleski's report to support his contention that the perineal application of talc caused Ms. Newsome to develop ovarian cancer. Dr. Godleski reports that he found 31 particles, which he claims represent talc in Ms. Newsome's tissues with 15 of the particles being found in the left ovary and only 1 particle in the right ovary. Of note, the left ovary, where Dr. Godleski claimed to find the vast majority of the talc particles, did not contain cancer. Additionally, there is no evidence of an inflammatory response in the areas were Dr. Godleski states that he found talc particles.

In his report, Dr. Clarke-Pearson states that he has performed a differential diagnosis and concluded that Ms. Newsome's endometrioid ovarian cancer was caused by the perineal application of talc. It is interesting to note that in prior testimony in February 2019, Dr. Clarke-Pearson concurred that we can never really know what causes ovarian cancer in any individual woman, stating:

A. What I think I understand your question being, if we can't identify a gene mutation, then we don't know what caused it. Is that what you're asking me?

Q. Yes.

A. Then the answer would be, yes, we don't know.[15]

Nonetheless, in deposition testimony in 2021, Dr. Clarke-Pearson stated that he can now determine the cause of an individual woman's ovarian cancer, retracting his prior testimony by stating, "Well, that was my answer at the time."[16] Yet even in that deposition, he almost immediately retreated to his prior opinion, agreeing that "there is no way to tell, in an individual woman who used talc, whether she got ovarian cancer because of her talc use" or would have developed it anyway. [17]

Dr. Clarke-Pearson also misapplied the epidemiological concept of an odds ratio to reach a conclusion on specific causation. In 2024, when initially asked if he attributed 30 percent of Ms. Newsome's ovarian cancer to her talc use, he replied "Yes."[18] Then, midway through this same deposition, he changed his opinion again and testified that 42% of Ms. Newsome's endometrioid carcinoma was attributable to her talc use (based on a table in the Penninkilampi meta-analysis).[19] This is a misapplication of epidemiological principles. A relative risk, even if it is affected by bias or other limitations, is not directly translatable to an individual's attributable risk of a cancer diagnosis.

---

[15] February 4, 2019 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 94, lines 4-11.
[16] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 215, line 2.
[17] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 248 line 7-p. 249, line 2.
[18] March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 306, lines 15-19.
[19] Penninkilampi, R., & Eslick, G. D. (2018). Perineal Talc Use and Ovarian Cancer. *Epidemiology*, 29(1), 41-49.

Conclusion

While Ms. Newsome states that she used baby powder daily from 1975-2015 for hygiene purposes, there is no credible scientific data to support the conclusion that the talc contributed to her development of ovarian cancer. The peer-reviewed scientific literature, nationally recognized and respected healthcare organizations (NCI, CDC, ACS, FDA), and the professional societies (SGO, ACOG) to which I belong, all maintain the position that talc does not cause ovarian cancer. All of the opinions herein are to a reasonable degree of medical probability. In addition, all of the general causation opinions contained in my General Expert Report dated May 21, 2024 are also incorporated herein.

MATERIALS RELIED ON AND CONSIDERED BY DR. CHERYL SAENZ

PLAINTIFF PROFILE FORM

1. 07/08/2020 Plaintiff Profile Form of Tamara Newsome

EXPERT REPORTS

1. 06/24/2021 Expert Report of John Godleski, MD
2. 07/02/2021 Expert Report of Daniel Clarke-Pearson, MD
3. 02/11/2022 Expert Report of Teri Longacre, MD
4. 11/15/2023 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD

DEPOSITION TRANSCRIPTS

1. 02/04/2019 Deposition Transcript of Daniel Clarke-Pearson, MD
2. 12/09/2020 Deposition Transcript of Tamara Newsome
3. 02/04/2021 Deposition Transcript of Ravin Garg, MD
4. 02/17/2021 Deposition Transcript of Albert Steren, MD
5. 05/13/2021 Deposition Transcript of Daniel Francois, Jr.
6. 05/14/2021 Deposition Transcript of Tael'lor Amelia Francois
7. 08/26/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 1)
8. 08/27/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 2)
9. 01/17/2024 Deposition Transcript of Daniel Clarke-Pearson, MD
10. 03/08/2024 Deposition Transcript of Daniel Clarke-Pearson, MD

MEDICAL RECORDS

1. AAMC Oncology and Hematology (NewsomeT-AAMCOH-00007-00327)
2. Annapolis Oncology Center (NewsomeT-AOCMR-00001-00280)
3. Anne Arundel Medical Center (NewsomeT-AAMC-00001-00008; NewsomeT-AAMCMR-00006-00493; NewsomeT-AAMCRad-00019-00022)
4. Capital Women's Care (NewsomeT-CWCMR-00001-00103)
5. Community Radiology Associates (NewsomeT-CRAMR-00001-00011)
6. Holy Cross Hospital (NewsomeT-HCHMR-00001-00405; NewsomeT-HCHPath-00008-00113; NewsomeT-HolyCrossHospPath-00001-00007; NewsomeT-HCHRad-00001-00014)
7. Muttah, Sureshkumar, MD (NewsomeT-SMMLMR-00001-00027)
8. Myraid Genetics (NewsomeT-MGIMR-00001-00018)
9. Plaintiff Produced Medical Records (NEWSOMET_AAMC_C_MDR000001-410; NEWSOMET_C_CAPI_MDR000001-100; NEWSOMET_CAPI_MDR000001-23; NEWSOMET_GARG_C_MDR000001-101; NEWSOMET_GARG_MDR000001-76;

NEWSOMET_HCH_MDR000001-43; NEWSOMET_MOHA_MDR000001-2; NEWSOMET_MUTTATH_C_MDR000001-81; NEWSOMET_MUTTATH_MDR000001-80; NEWSOMET_PWHS_MDR000001-3; NewsomeT-MOHA-MDR-000003-000029; NEWSOMET-REC00001-10; NewsomeT-WHSMR-00001-00020; NewsomeT-PPR-00085-00296)

10. Quest Diagnostics (NewsomeT-QDNISJC-00001-00058)
11. Supervalu Pharmacy (NewsomeT-SFP-00001-00023; NewsomeT-SPCO-00001-00023)
12. Target Compliance (NewsomeT-TPCO-00001-00006)
13. Washington Adventist Hospital (NewsomeT-WAHMR-00001-00075; NewsomeT-WAHMRPharm-00006-00020; NewsomeT-WAHRad-00001-00004)
14. White Oak Medical Center (NewsomeT-WOMCMR-00006-00088; NewsomeT-WOMCRad-00002-00007)
15. Women's Health Specialists of Montgomery County (NewsomeT-WHSMCLMR-00001-00019; NewsomeT-WHSMCLMR-00025-00098)

LITERATURE

1. Olsen C.M., Nagle, C.N., Whiteman, D.C., Ness R., Pearce C.L., Pike M., Rossing M.A., Terry K., Wu A., et al. (2013). Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. *Endocr Relat Cancer*, 20(2): 251-62.
2. Penninkilampi, R., & Eslick, G. D. (2018). Perineal Talc Use and Ovarian Cancer. *Epidemiology*, 29(1): 41-49.
3. Saavalainen, L., Lassus H., But A., Tiitinen A., Harkki P., Gissler M., Pukkala E., Heikinheimo O. (2018). Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology*. 131(6): 1095-1102.

ADDITIONAL MATERIALS

1. Saed Confidential Documents (SAED_SEPT222021_SUPPL_000001-399)